

CLAIMS

1. A method of detecting the presence of target polynucleotide of TREPA in a test sample, comprising:

- (a) contacting said test sample with at least one TREPA specific polynucleotide or complement thereof; and
- (b) detecting the presence of said target polynucleotide of TREPA in the test sample, wherein said TREPA specific polynucleotide has at least 50% identity to polynucleotide SEQUENCE ID NO 1 and fragments, analogs or complements thereof.

2. The method of claim 1 wherein said target polynucleotide of TREPA is attached to a solid phase prior to performing step (a).

3. A method for detecting mRNA of TREPA in a test sample, comprising:

- (a) performing reverse transcription with at least one primer in order to produce cDNA;
- (b) amplifying said cDNA obtained from step (a) by using other oligonucleotide primer(s) of TREPA as sense and antisense primer(s) in a first-stage amplification to obtain TREPA amplicon; and
- (c) detecting the presence of said TREPA amplicon in the test sample, wherein said oligonucleotide primers of TREPA have at least 50% identity to SEQUENCE ID NO 1 and fragments, analogs or complements thereof.

4. The method of claim 3 wherein said test sample is reacted with a solid phase prior to performing step (a) or step (b) or step (c).

5. The method of claim 3, wherein said detection step comprises utilizing a detectable label capable of generating a measurable signal.

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6. A method of detecting target TREPA polynucleotide in a test sample suspected of containing said target, comprising:

(a) contacting said target TREPA polynucleotide with at least one TREPA oligonucleotide as a sense primer and with at least one TREPA oligonucleotide as an anti-sense primer and amplifying same to obtain a first stage reaction product;

(b) contacting said first stage reaction product with at least one other TREPA oligonucleotide, with the proviso that the other TREPA oligonucleotide is located 3' to the TREPA oligonucleotides utilized in step (a) and is complementary to said first stage reaction product; and

(c) detecting said target TREPA polynucleotide, wherein said TREPA oligonucleotides utilized in step (a) and step (b) have at least 50% identity to SEQUENCE ID NO 1 and fragments, analogs or complements thereof.

7. The method of claim 6, wherein said test sample is reacted with a solid phase prior to performing step (a) or step (b) or step (c).

8. The method of claim 6, wherein said detection step comprises utilizing a detectable label capable of generating a measurable signal.

9. The method of claim 8, wherein said detectable label is reacted to a solid phase.

10. A test kit useful for detecting TREPA polynucleotide in a test sample, comprising a container containing at least one TREPA polynucleotide having at least 50% identity to SEQUENCE ID NO 1 and fragments, analogs or complements thereof.

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11. A purified polynucleotide or fragment thereof derived from TREPA gene wherein said purified polynucleotide is capable of selectively hybridizing to the nucleic acid of said TREPA gene, and wherein said purified polynucleotide has at least 50% identity to SEQUENCE ID NO 1 and fragments, analogs or complements thereof.

12. The purified polynucleotide of claim 11 wherein said purified polynucleotide is produced by recombinant techniques.

13. The purified polynucleotide of claim 12 wherein said polynucleotide produced by recombinant techniques comprises a sequence of at least one epitope encoded by TREPA.

14. A recombinant expression system comprising a nucleic acid sequence that encodes an open reading frame derived from TREPA which is operably linked to a control sequence compatible with a desired host and wherein said nucleic acid sequence has at least 50% identity to SEQUENCE ID NO 1 and fragments, analogs or complements thereof.

15. The recombinant expression system of claim 14 further comprising a cell transformed with said recombinant expression system.

16. A polypeptide encoded by TREPA, wherein said polypeptide has at least 35% identity to amino acid sequence selected from the group consisting of SEQUENCE ID NO 2, SEQUENCE ID NO 3 and fragments thereof.

17. The polypeptide of claim 16 wherein said polypeptide is produced by recombinant technology.

18. The polypeptide of claim 16 wherein said polypeptide is produced by synthetic techniques.

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19. A compound which inhibits activation of the TREPA polypeptide of claim 16.

20. The polypeptide of claim 16, wherein said polypeptide is a soluble fragment of the TREPA protein and is capable of binding a receptor for TREPA.

21. A method for treating a patient having a need to induce activation of the TREPA polypeptide of claim 16, comprising administering to said patient a therapeutically effective amount of a compound which induces activation of the TREPA polypeptide of claim 16.

22. A method for determining whether a compound is an agonist or antagonist to TREPA protein, comprising:

- (a) contacting a cell having TREPA protein expressed on its surface with said compound and a receptor ligand;
- (b) determining whether a biological effect is produced from the interaction of said cell and said compound; and
- (c) determining whether said compound is an agonist or antagonist.

23. A method for determining whether a receptor binds to a TREPA ligand, comprising:

- (a) contacting a mammalian cell which expresses the TREPA ligand with a receptor;
- (b) detecting the presence of the receptor; and
- (c) determining whether the receptor binds to the TREPA ligand.

24. An antibody which specifically binds to at least one epitope encoded by TREPA, wherein said antibody is polyclonal or monoclonal and wherein said epitope comprises an amino acid sequence having at least 35% identity to an

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amino acid sequence selected from the group consisting of SEQUENCE ID NO 2, SEQUENCE ID NO 3 and fragments thereof.

25. An assay kit for determining the presence of TREPA antigen or antibody in a test sample, comprising a container containing a TREPA polypeptide having at least 35% identity to an amino acid sequence selected from the group consisting of SEQUENCE ID NO 2, SEQUENCE ID NO 3 and fragments thereof.

26. The assay kit of claim 25 wherein said polypeptide is attached to a solid phase.

27. An assay kit for determining the presence of TREPA antigen or antibody in a test sample, comprising a container containing an antibody which specifically binds to TREPA antigen, wherein said antigen comprises at least one epitope of TREPA having at least about 60% similarity to a sequence selected from the group consisting of SEQUENCE ID NO 2, SEQUENCE ID NO 3 and fragments thereof.

28. The kit of claim 27 wherein said antibody is attached to a solid phase.

29. A method for producing a polypeptide comprising at least one epitope of TREPA, which method comprises incubating host cells transformed with an expression vector, wherein said vector comprises a polynucleotide sequence encoding a polypeptide, which polypeptide comprises an amino acid sequence having at least 35% identity to an amino acid sequence selected from the group consisting of SEQUENCE ID NO 2, SEQUENCE ID NO 3 and fragments thereof.

30. A method for detecting TREPA antigen in a test sample suspected of containing said TREPA antigen, comprising:

(a) contacting said test sample with an antibody or fragment thereof which specifically binds to at least one

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epitope of TREPA antigen selected from the group consisting of SEQUENCE ID NO 2, SEQUENCE ID NO 3 and fragments thereof, for a time and under conditions sufficient for the formation of antibody/antigen complexes; and

(b) detecting said complexes.

31. The method of claim 30 wherein said antibody is attached to a solid phase.

32. A method for detecting antibodies which bind to TREPA antigen in a test sample suspected of containing said antibodies, comprising:

(a) contacting said test sample with a TREPA polypeptide, wherein said TREPA polypeptide contains at least one TREPA epitope comprising an amino acid sequence or fragment thereof having at least 35% identity to an amino acid sequence selected from the group consisting of SEQUENCE ID NO 2, SEQUENCE ID NO 3 and fragments thereof, for a time and under conditions sufficient to allow antigen/antibody complexes to form;

(b) detecting said complexes.

33. The method of claim 32 wherein said TREPA polypeptide is attached to a solid phase.

34. A tissue culture grown cell comprising a nucleic acid sequence that encodes at least one epitope of TREPA antigen or a fragment thereof, wherein said nucleic acid sequence is transfected into said cell and wherein said nucleic acid sequence is SEQUENCE ID NO 1 and fragments, analogs or complements thereof.

35. A method for producing antibodies which specifically bind to TREPA antigen, comprising administering to an individual an isolated immunogenic polypeptide or fragment thereof, wherein said isolated immunogenic polypeptide comprises at least one TREPA epitope and has at

least 35% identity to a sequence selected from the group consisting of SEQUENCE ID NO 2, SEQUENCE ID NO 3 and fragments thereof, in an amount sufficient to produce an immune response.

36. A method for producing antibodies which specifically bind to TREPA antigen, comprising administering to a mammal a plasmid comprising a sequence which encodes at least one epitope of TREPA, where said TREPA sequence is selected from the group consisting of SEQUENCE ID NO 1 and fragments or complements thereof.

37. A composition of matter comprising a TREPA polynucleotide or fragment thereof, wherein said polynucleotide has at least 50% identity to SEQUENCE ID NO 1 and fragments, analogs or complements thereof.

38. A composition of matter comprising a polypeptide containing at least one epitope encoded by TREPA, wherein said polypeptide has at least 35% identity to a sequence selected from the group consisting of SEQUENCE ID NO 2, SEQUENCE ID NO 3 and fragments thereof.

39. The composition of matter of claim 38, wherein said polypeptide is a soluble fragment of the TREPA protein and is capable of binding a receptor for TREPA.

40. The test kit of claim 10 further comprising a container containing tools useful for collection of said sample selected from the group consisting lancets, absorbent paper, cloth, swabs and cups.

41. The assay kit of claim 25 further comprising a container containing tools useful for collection of said sample selected from the group consisting lancets, absorbent paper, cloth, swabs and cups.

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42. The test kit of claim 27 further comprising a container containing tools useful for collection of said sample selected from the group consisting lancets, absorbent paper, cloth, swabs and cups.

43. A gene or fragment thereof which codes for TREPA protein which comprises an amino acid sequence which has at least 35% identity to SEQUENCE ID NO 5.

44. A gene or fragment thereof comprising DNA having at least 35% identity to SEQUENCE ID NO 4.

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